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Reuse of Balloon Catheters for Coronary Angioplasty: A Potential Cost-Saving Strategy?

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Objectives. **This study was designed to determine the effectiveness, safety and costs associated with reuse of angioplasty catheters and to compare these results with those of a contemporary center that employed a single-use strategy.**

Background. **Coronary angioplasty is an important but expensive procedure. To overcome the financial constraints of the Canadian health care system, reuse of angioplasty catheters is routinely practiced in some institutions.**

Methods. **In a prospective observational study, data forms were completed after each angioplasty procedure and before patient discharge over a 10-month period.**

Results. **A total of 693 patients underwent coronary angioplasty in the two centers. Clinical and lesion characteristics were similar except for a higher incidence of unstable angina at the reuse center ($p < 0.005$). The angiographic success rate was identical (88%) at both centers. The reuse center utilized more balloon catheters/lesion (mean ± SD 2.4 ± 1.5 vs. 1.2 ± 0.5, $p < 0.00001$) and had a higher incidence of initial balloon failure (10.2% vs. 3.3%, $p < 0.0001$). Significant prolongation of the procedure time (81 ± 41 vs. 68 ± 32 min, $p < 0.0001$) and increased volume of contrast medium (201 ± 86 vs. 165 ± 61 ml, $p < 0.0001$) were seen in the reuse center. A higher rate of adverse clinical events (7.8% vs. 3.8%, $p < 0.025$) was observed in the reuse center, especially in patients with unstable angina.**

Conclusions. **The reuse strategy was associated with a higher rate of adverse events, prolonged procedure time and increased use of contrast medium, especially in lesions that were not crossed by the initial balloon and in patients with unstable angina. Whether these differences are related to the reuse strategy or to differences in patient groups cannot be ascertained by this observational study. A multicenter randomized trial is required to further assess the safety and the cost/benefit ratio of this strategy.**

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Coronary angioplasty has gained widespread acceptance in the treatment of atherosclerotic coronary artery disease, with >400,000 interventions performed in the United States in 1993 and an estimated 800,000 cases worldwide. The equipment and personnel costs incurred with this procedure are substantial and affect the health care system. To overcome the financial constraints of the Canadian system, some institutions have adopted the practice of reusing balloon catheters that, according to manufacturer's instructions, are intended for single use only. Studies (1–3) have demonstrated that with careful cleaning and ethylene oxide sterilization performed according to systematic and standardized guidelines, the risks of infection and pyrogenic reactions are not significantly higher than those associated with new catheters. Furthermore, in vitro testing has shown that the physical and mechanical properties of the balloon catheters can be maintained after multiple uses provided that close surveillance is used to withdraw unacceptable balloons. However, a careful clinical evaluation of balloon catheter reuse has not been performed.

In this observational study, angioplasty results were recorded prospectively at two contemporary Canadian institutions that had in common a comparable number of angioplasty procedures and case selection but differed in that one center (St. Michael's Hospital) used a conventional strategy of single-use only for balloon catheters, whereas the other center (Centre Hospitalier Universitaire de Sherbrooke) reused such catheters many times. In this study, we tried to determine whether this difference in balloon catheter use was associated with significant differences in angiographic and clinical success rates and in the number of adverse clinical events. We also compared several important details affecting the overall cost and risks of the angioplasty procedure, including procedure duration, fluoroscopy time, volume of contrast agent used and the number of catheters required per lesion.

Methods

The study protocol was approved by the ethics committees of both hospitals. All patients undergoing coronary angioplasty at the two centers were included in the study unless an

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alternative form of coronary intervention (e.g., stent, excimer laser) had been used initially. Coronary angioplasty was performed according to standard practice with a steerable, movable guide wire system placed through the femoral route, with either over the wire or monorail systems, according to operator preference. In the reuse center, the angioplasty operator was aware of the number of previous uses of a catheter and could request a new balloon at any time during the procedure. If multiple balloons were used during a procedure, no attempt was made to select only balloons with the same number of reuses. Nonionic contrast medium was used in both institutions. Data forms were completed at the end of each procedure and at the time of hospital discharge. In addition to patient and lesion characteristics, procedure duration (time elapsed between arterial puncture and removal of the guide wire and the guiding catheter), fluoroscopy time and volume of contrast medium used were also recorded. Temperatures were recorded 1 h before angioplasty and every 8 h during the 1st 24 h after the procedure (starting 1 h after angioplasty) and at least once daily until hospital discharge. Blood was drawn for measurement of creatine kinase (CK) levels before and at 8 and 24 h after the procedure.

Angiographic success was defined as a lesional residual stenosis <50%, as determined by visual assessment. Clinical success was defined as an angiographically successful angioplasty of all attempted lesions, without any procedure-related in-hospital adverse clinical event, defined as death, myocardial infarction, stroke, emergency angioplasty or bypass surgery. Elective bypass surgery performed during the same admission for failed angioplasty without a complication was not counted as an adverse clinical event. Clinical failure was designated when all attempted lesions could not be dilated successfully. Abrupt closure was any postangioplasty Thrombolysis in Myocardial Infarction (TIMI) flow grade ≥2 that became ≤1 with occurrence of either chest pain or an ST segment shift ≥1 mm. Fever was noted when the recorded temperature was >38°C buccal or 38.5°C rectal. Standard criteria for classification of unstable angina (4) and non-Q and Q wave myocardial infarction were used (5,6).

Catheter reuse protocol. Immediately after completion of the angioplasty procedure, the catheter was inspected for deformities of the shaft and balloon. If the catheter was without visible flaws, the outer surface was cleaned with tap water to remove blood. For monorail catheters, the wire entry site was flushed thoroughly with tap water through a syringe loaded with a blunt needle. Passage of a wire through the monorail lumen to ensure that no obstructions were present was followed by further water flushing. For over the wire systems, the proximal port was forcibly flushed with tap water. For the balloon port, complete removal of contrast medium was necessary to prevent crystallization within the balloon to ensure proper balloon function and further use of the catheter. For this purpose negative pressure was applied multiple times with a 50-ml plastic syringe to remove the mixture of contrast medium and sterile water that had been used during the procedure to fill the balloon. The balloon was maintained under negative pressure with a three-way stopcock. Next, tap water was injected two to three times under manual pressure to fully inflate the balloon and then removed with application of negative pressure to progressively dilute the concentration of contrast medium within the balloon. When the contrast agent was suitably replaced with tap water, the balloon was emptied under negative pressure and then filled with air alone until no more liquid was visible inside the inflated balloon. The syringe was removed and the balloon port was left open to air. The catheter was then dried for 24 h at 37°C. The metallic protector supplied by the manufacturer in new balloons was reinserted in the distal balloon catheter lumen to permit manual reshaping of the balloon; then the plastic sleeve that had covered the balloon tip before its first use was reapplied to maintain a low balloon profile and thus avoid a "beavertail" appearance with an unacceptable profile. The balloon catheter was then repackaged and sent for gas sterilization with ethylene oxide. Before the next balloon use, the outer surface of the balloon was carefully inspected (but to maintain a low profile, the balloon was not reinflated), and the operator determined whether or not to proceed with the balloon catheter. The cost of preparing a single balloon catheter for reuse has been calculated at $30* (including personnel time, packaging and gas sterilization). The average cost of a new balloon catheter at the reuse and the single-use site was $800 and $537, respectively. The formula used to calculate the cost/balloon use at the reuse center was $[800 + ([n - 1] \times 30)]/n$, where n = the current number of times the balloon had been used (which averaged 6.2 for the reuse group, as the mean number of previous uses in the study was 5.2), and $30 = estimated cost of reuse (see earlier). The overall cost/lesion was then obtained by multiplying the cost/balloon by the number of balloons used per lesion.

Statistics. Data are expressed as mean value ± SD. Comparisons between the two centers were performed by Student *t* tests for continuous variables and chi-square analysis for discrete variables. A statistical probability <0.05 was considered to indicate significance.

Results

The study group consisted of 693 patients with 853 lesions who underwent coronary angioplasty at one of the two study centers. The baseline patient and angiographic characteristics of the two groups (Table 1) indicate that the centers were comparable except for a higher incidence of unstable angina (70% vs. 57%, $p < 0.005$) and intravenous heparin (42% vs. 35%) and nitroglycerin infusions (25% vs. 15%) in patients at the reuse center. The procedural results (Table 2), showed an identical rate of angiographic success (88%) in the two groups. However, an increased incidence of abrupt vessel closure (during and after the procedure) occurred in the reuse center (6.7% vs. 3.3%, $p < 0.025$), and ~50% of vessels were successfully reopened at both centers. Although a much higher proportion of

*All costs in this study are expressed in Canadian dollars.

Table 1. Clinical Baseline Data

	St. Michael's*	Sherbrooke†	p Value
Patients/lesions (no.)	373/452	320/401	
Age (yr)	60 ± 11	61 ± 11	
Male	271 (73%)	229 (72%)	
CCS class			
I–II	83 (22%)	74 (23%)	
III–IV	290 (78%)	245 (77%)	
Clinical setting			
Stable angina	159 (43%)	88 (27.5%)	< 0.005
Unstable angina	213 (57%)	224 (70%)	
Acute MI	1 (0.3%)	8 (2.5%)	
IV heparin	131 (35%)	134 (42%)	<0.1
IV nitroglycerin	54 (15%)	81 (25%)	< 0.0005
IV heparin after PTCA	92 (25%)	263 (82%)	< 0.0001
Extent of CAD			
1-vessel	221 (59%)	192 (60%)	
2-vessel	99 (27%)	104 (32.5%)	
3-vessel	53 (14%)	69 (7.5%)	
PTCA procedure type			
Single vessel	345 (92%)	297 (93%)	
Single segment	292 (78%)	248 (78%)	
Multisegment	53 (14%)	49 (15%)	
Multivessel	28 (8%)	23 (7%)	
Lesion type			
Primary	370 (82%)	329 (82%)	
Restenosis	82 (18%)	72 (18%)	
Total occlusions (TIMI flow grade 0–1)	57 (13%)	58 (15%)	
Vessel			
LMCA	2 (<1%)	1 (<1%)	
LAD	229 (51%)	177 (44%)	
LCx	86 (19%)	84 (21%)	
RCA	120 (27%)	125 (31%)	
Graft	15 (3%)	14 (3%)	

*Single-use balloon catheter strategy. †Multiuse strategy. Values presented are mean value ± SD or number (%) of patients. CAD = coronary artery disease; CCS = Canadian Cardiovascular Society; IV = intravenous; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LMCA = left main coronary artery; MI = myocardial infarction; PTCA = percutaneous transluminal coronary angioplasty; RCA = right coronary artery; TIMI = Thrombolysis in Myocardial Infarction.

patients in the reuse center than in the single-use center received intravenous heparin after the procedure (82% vs. 25%, $p < 0.0001$), abrupt vessel closure occurred more frequently outside the catheterization laboratory in the reuse group (3.0% vs. 0.7%, $p < 0.01$). The rate of unsuccessful crossing with the initial balloon catheter also was higher in the reuse group (10.2% vs. 3.3%, $p < 0.0001$). The number of guiding catheters/lesion was slightly but significantly increased at the reuse center (1.3 ± 0.7 vs. 1.2 ± 0.5, $p < 0.02$), but the mean number of guide wires/lesion was identical. The reuse center used twice the number of balloon catheters/lesion (2.4 ± 1.5 vs. 1.2 ± 0.5, $p < 0.00001$). Procedure times and contrast medium use were significantly greater (by ~20%) in the reuse center. Fluoroscopy times were not significantly different in the two centers. There were two cases of balloon rupture (at 9 and 12 atm, respectively) in the study, both occurring at the reuse center in balloons with two previous uses, in addition to a leak in the shaft of a balloon (three previous uses) that required continuous pressure application to maintain complete balloon inflation.

Overall clinical success rate and the rate of clinical failure without adverse clinical events were comparable in the two centers (Table 3). The rate of clinical failure with adverse clinical events was significantly higher in the reuse group (7.8% vs. 3.8%, $p < 0.025$). Adverse clinical events are detailed in Table 4. Among patients with unstable angina, particularly patients with angina at rest, those in the reuse group had a significantly greater number of adverse clinical events than did those in the single-use group; in contrast, no significant intergroup differences in adverse events were seen in patients with stable angina (Table 5).

A significantly higher proportion of failures of first balloons to cross the lesion occurred in the reuse center (10.2% vs. 3.3%) (Table 2), and in both centers initial balloon failure was associated with a higher rate of adverse clinical events and significantly greater contrast volume, fluoroscopy time and procedure duration, than those associated with initial balloon success in crossing a lesion (Table 6). The actual number of previous balloon reuses did not have a significant impact on

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Table 2. Procedural Results

	St. Michael's*	Sherbrooke†	p Value
Per lesion			
Lesions	452	401	
Lesions crossed with guide wire	431 (95.3%)	375 (93.5%)	
Lesions not crossed with the first balloon catheter	15 (3.3%)	41 (10.2%)	< 0.0001
Lesions crossed with guide wire and any balloon catheter	422 (93.4%)	372 (92.8%)	
Angiographic success	399 (88%)	353 (88%)	
Abrupt closure			
Inside cath lab	12 (2.6%)	15 (3.7%)	
Outside cath lab	3 (0.7%)	12 (3.0%)	< 0.01
Total	15 (3.3%)	27 (6.7%)	< 0.025
Vessel reopened	8 (1.8%)	12 (3.0%)	
Vessel not reopened	7 (1.5%)	15 (3.7%)	
Guide wires	1.3 ± 0.6	1.3 ± 0.8	
Guiding catheters	1.2 ± 0.5	1.3 ± 0.7	< 0.02
Balloon catheters	1.2 ± 0.5	2.4 ± 1.5	< 0.00001
Balloon catheter reuses	—	5.2 ± 2.7	
Per patient			
Constrast volume (ml)	165 ± 61	201 ± 86	< 0.0001
Procedure time (min)	68 ± 32	81 ± 41	< 0.0001
Fluoroscopy time (min)	17.1 ± 9.9	17.9 ± 11.2	
Hospital stay (days)	3.4 ± 2.8	5.1 ± 5.7	< 0.0001
Median	2.0	3.0	

*Single-use balloon catheter strategy. †Reuse strategy. Unless otherwise indicated, values presented are mean value ± SD or number (%) of lesions. cath lab = catheterization laboratory.

initial balloon crossing, although new balloons were used as a first balloon in only 24 lesions at the reuse center.

Fever was noted in only three patients in the reuse group (in association with urinary tract infection, pneumonia and the postoperative period after urgent bypass surgery) and in one patient in the single-use center (flulike illness), and in all cases it did not appear to be related to the catheterization procedure.

Catheter costs per lesion were $370 and $644 at the reuse and single-use centers, respectively, which was a saving of $274/lesion, corresponding to a 43% reduction in the reuse center. In the reuse center, this saving amounted to ~$110,000 over the course of the study.

Discussion

Cost containment in health care has become an increasingly important issue worldwide. In Canada, we have limited budgets for funding of angioplasty programs that must meet the expectations of the general population and the cardiologic community. Balloon catheter reuse has been adopted by several institutions in Canada to maintain these programs. This practice has raised important concerns, particularly with respect to added risks to the patient including infection, pyrogenic reactions and catheter integrity and embolism as well as risks to staff members who clean and sterilize the catheters. In addition, environmental issues related to waste associated with widespread use of disposable instruments versus the potential toxicity of resterilization methods have been debated. To reflect contemporary Canadian practice, we compared the results of a reuse center (Sherbrooke) with those of a single-use center (St. Michael's) that performed a similar number of procedures/year.

Table 3. In-Hospital Outcome

	St. Michael's*	Sherbrooke†	p Value
Patients	373	320	
Clinical success	312 (83.6%)	259 (80.9%)	
Clinical failure	61 (16.4%)	61 (19.1%)	
No adverse clinical event	47 (12.6%)	36 (11.3%)	
With adverse clinical event	14 (3.8%)	25 (7.8%)	< 0.025

*Single-use balloon catheter strategy. †Reuse strategy. Values presented are number (%) of patients.

Table 4. Adverse Clinical Events

	St. Michael's*	Sherbrooke†	p Value
Late closure	3 (0.8%)	12 (3.8%)	< 0.01
Myocardial infarction			
Q wave	0	1 (0.3%)	
Non-Q wave	6 (1.6%)	9 (2.8%)	
Total	6 (1.6%)	10 (3.1%)	
CABG			
Urgent	4 (1.1%)	13 (4.1%)	< 0.025
Nonurgent	3 (0.8%)	5 (1.5%)	
Death			
During PTCA	0	0	
After PTCA	3 (0.8%)	6 (1.9%)	

*Single-use balloon catheter strategy. †Reuse strategy. Values presented are number (%) of patients. CABG = coronary artery bypass graft surgery; PTCA = percutaneous transluminal coronary angioplasty.

Table 5. Clinical Success Rate and Adverse Clinical Events According to Baseline Clinical Setting

	St. Michael's*			Sherbrooke†		
	Patients	Clinical Success	Adverse Clinical Event	Patients	Clinical Success	Adverse Clinical Event
Stable angina	159	130 (82%)	4 (2.5%)	88	74 (84%)	1 (1.1%)
Unstable angina						
Progressive	43	38 (88%)	1 (2.3%)	82	72 (88%)	5 (6.1%)
At rest	81	65 (80%)	3 (3.7%)‡	73	52 (71%)	9 (12.3%)‡
Post-MI angina	89	78 (88%)	6 (6.7%)	69	55 (80%)	8 (11.6%)
<48 h	2	1 (50%)	1 (50%)	8	6 (75%)	1 (12.5%)
48 h–2 wk	54	48 (89%)	3 (5.6%)	34	28 (82%)	4 (11.8%)
2–12 wk	35	29 (88%)	2 (6.1%)	27	21 (78%)	3 (11.1%)
Total	213	181 (85%)	10 (4.7%)	224	179 (80%)	22 (9.8%)‡
Acute MI	1		1 (100%)	8	6 (75%)	2 (25%)

*Single-use balloon catheter strategy. †Reuse strategy. ‡$p < 0.05$. Sherbrooke versus St. Michael's. Values presented are number (%) of patients. MI = myocardial infarction.

Catheter performance and safety. Although a significantly higher proportion of first balloons in the reuse center than in the single-use center (10.2% versus 3.3%) could not cross the lesion, the two centers had a similar angiographic success rate. Initial balloon failure was associated in both centers with a higher rate of adverse clinical events and significantly greater contrast volume, fluoroscopy time and procedure duration, than those associated with initial balloon success in crossing a lesion.

In addition to increased use of contrast medium and procedure duration, there was a significant increase in the incidence of abrupt vessel closure and of adverse clinical events at the reuse center, although the success and complications rates were within the range previously reported for the National Heart, Lung and Blood Institute registry (7–9). The presence of unstable angina seemed to be an important factor in the significant differences in the rate of adverse clinical events between the two centers. There were no differences between these centers in clinical success rates or complication rates in patients with stable angina. Because the single-use center had similar results in patients with stable and unstable angina, the poorer results in patients with unstable angina in the reuse group may be attributable to the reuse strategy. A potential explanation may be the additional trauma to the vessel required to cross lesions with reused balloons that have lost surface coatings that enhance ability to glide or have less optimal profiles than those of new balloons but whose defects are not obviously visible to the operator during the preprocedural inspection.

Failure to cross a lesion with the initial balloon is probably a consequence of balloon reuse because such lesions were eventually crossed in 38 of 41 cases after further balloon exchanges in the reuse center but in only 5 of 15 cases at the single-use center, which used only new (and presumably lower profile) balloon catheters. There may also have been cases in which the reused balloon was able to cross the lesion but required more push and manipulation than would be needed for a new balloon. Therefore, although most lesions eventually can be crossed and dilated successfully with reused balloons, use of these balloons may involve more force and trauma to the wall, resulting in higher complication rates in predisposed lesions such as those in patients with unstable angina. Lesions associated with stable angina may be less fragile and less likely to occlude with such manipulations.

Table 6. Influence of First Balloon Catheter Performance on Outcome and Procedural Results

	St. Michael's*		p Value	Sherbrooke†		p Value
	Successful Crossing	Unsuccessful Crossing		Successful Crossing	Unsuccessful Crossing	
Lesions	416 (92%)	15 (3.6%)		334 (83%)‖	41 (12.3%)‖	
Patients	348 (93%)	14 (4.0%)		273 (85%)§	40 (14.7%)§	
Abrupt closures (overall)	12 (2.9%)	2 (13.3%)	< 0.05	21 (6.3%)‡	6 (14.6%)	< 0.1
Clinical events	12 (3.4%)	1 (7.1%)		19 (7.0%)‡	4 (10%)	
Procedure time (min)	65 ± 33	90 ± 33	< 0.001	79 ± 41§	109 ± 42	< 0.01
Contrast volume (ml)	160 ± 67	156 ± 47		200 ± 86‖	209 ± 80‖	
Fluoroscopy time (min)	15.8 ± 9.3	29.4 ± 14.9	< 0.001	16.6 ± 10.2	26.3 ± 14.4	< 0.001
Balloon catheters (no.)	1.2 ± 0.4	1.8 ± 0.6	< 0.001	2.3 ± 1.2‖	4.3 ± 1.7‖	< 0.0001

*Single-use balloon catheter strategy. †Reuse strategy. §$p < 0.05$, ‖$p < 0.0001$, ‡$p < 0.0001$. Sherbrooke versus St. Michael's. Values presented are number (%) of variable in first column or mean value ± SD.

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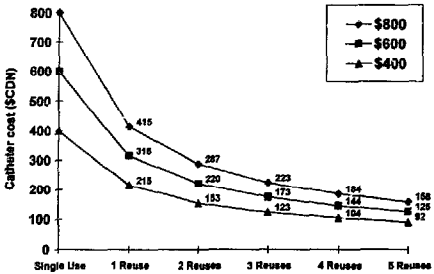

Figure 1. Calculated savings based on baseline cost ($800, $600 or $400 in Canadian dollars [$CDN]) and number of reuses, assuming a cost of $30/catheter reuse. The following formula was used to calculate the cost/balloon use: $\{800 + [(n - 1) \times 30]\}/n$, where n = the current use of the balloon. The curves show that most of the potential savings are obtained after two reuses.

Cost-effectiveness. This study demonstrated important catheter cost differences between the two centers. There was an estimated saving of $110,000 over the 10-month course of the study in the reuse center, which had an average of 5.2 balloon catheter reuses. However, the financial downside of this strategy appeared to be significant increases in procedure time and contrast medium volumes, presumably in response to the increased number of balloon catheters and exchanges. Furthermore, the additional costs associated with in-hospital adverse events (e.g., increased rates of bypass surgery and myocardial infarction, prolonged procedure time and hospital stay) may be offsetting.

Limitations of the study. This observational study has several limitations. The main limitation is that patients were not randomized to receive either new or reused balloons. The selection of a concurrent control group consisting of patients at a second center may be not be entirely suitable because of differences in patient groups, practice patterns and operator experience.

Patient groups. Although the two centers treated a similar number of patients, important differences in the incidence of unstable angina (and related intravenous heparin and nitroglycerin use before the procedure) between the two centers suggest that more high risk lesions were attempted at the reuse center. Therefore, significant differences in the incidence of unstable angina could partly explain the higher incidence of adverse events at the reuse center. However, this poorer outcome may also be related to the practice of catheter reuse, because such reuse appeared to have detrimental effects on the procedure, including a higher rate of failure of initial balloon crossing, prolonged procedure time and increased volume of contrast medium.

Practice patterns. The average number of catheters/lesion was two times higher in the reuse center. Although this difference may be attributable to the performance of reused catheters, it may also be related to the dilation strategy used when balloon costs are reduced. In fact, some operators at the reuse center used progressive balloon size dilation because they believed that this technique was safer than matching the vessel reference diameter with the first balloon. The effects on patient outcome of the increased number of intracoronary manipulations inherent in such a dilation strategy are unknown. This strategy would probably not be used in a single-use center because of financial concerns. Similarly, decisions to select another balloon to marginally improve a lesion were less affected by cost considerations in the reuse center than at the single-use center. Whether the differences in the rate of adverse clinical events reflect differences that result from the use of resterilized catheters or simply differences in practice patterns between centers cannot be ascertained by this study because patients were not randomized within an institution.

Operator experience. This observational study compared the angioplasty results of two different centers performing a similar number of procedures/year but with different operators. However, comparison of the procedural results showed that a similar number of lesions could be successfully crossed with the guide wire in the two centers (Table 2). Despite a higher failure rate of the initial balloon in the reuse center, the percent of lesions that were crossed with a balloon catheter was similar to that at the single-use center. Finally, the angiographic success rate was identical (88%) in the two centers. These data, taken together with the use of resterilized balloon catheters (with presumably higher profiles) at the reuse center, suggest that operator experience and skills were probably comparable between the two centers.

Clinical implications. Several issues concerning catheter reuse must be emphasized. Before a policy of balloon catheter reuse is initiated, it is imperative to establish clear and rigorous guidelines for cleaning and sterilization with adequate monitoring and quality control in place at all stages of the procedure. In calculating the proposed savings of this strategy, costs of preparing and packaging the catheters must be considered and balanced against the savings/catheter based on the baseline price and number of possible reuses (Fig. 1). In a recent report from the Council of Health Technologies in Quebec (1), an economic analysis showed that most of the savings were gained after three reuses.

In small and medium volume centers (250 to 500 procedures/year), a reuse strategy may be even more cost-saving than in larger centers where bulk purchasing can significantly reduce the individual cost per catheter to a level possibly approaching costs of a reused catheter in our study. Finally, the clinical safety of catheter reuse remains to be established, and the results of this observational study indicate the need for a large randomized trial. If the rate of adverse clinical events is in fact higher with reused catheters, the additional costs associated with these complications (e.g., increased rates of bypass surgery and myocardial infarction, prolonged procedure time and hospital stay) may counteract the financial benefits.

Conclusions. The data from this study demonstrate that a strategy of balloon catheter reuse can result in significant balloon catheter savings and acceptable angioplasty success rates. However, the strategy may decrease the safety of the procedure to a level lower than that associated with a single-use strategy, resulting in higher rates of abrupt vessel closure and of adverse clinical events, particularly in unstable lesions. In addition, there may be some increased costs related to other procedural variables (increased use of contrast medium, longer procedure duration). It is important to include these additional costs in assessing the overall cost/benefit ratio of a reuse strategy. This observational study raises important questions regarding a strategy of reuse, and a randomized trial is planned in Quebec to definitively test the hypotheses that complications in angioplasty procedures performed with new versus reused balloons are equivalent and that the reuse strategy is cost-effective. This trial will also address the issue of reused catheters in patients with unstable angina.

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